

material having a plurality of interstices for holding fusion promoting material, said implant being made of a material appropriate for human implantation.

#### REMARKS

Applicant respectfully brings to the Examiner's attention that five (5) signed Form PTO 1449's submitted with the Information Disclosure Statements dated: July 9, 1997; December 19, 1997; January 14, 1999; June 30, 1999; and November 3, 1999, have yet to be received by the applicant. It is respectfully requested that the Examiner provide copies of all five (5) signed Form 1449's to the applicant, copies of which are attached hereto for the Examiner's convenience.

Applicant amended each of the independent claims to recite that claimed invention is directed to a "non-threaded" spinal fusion implant. Applicant amended the specification and the drawings to correct minor informalities. In particular, reference numbers 222, 234 and 236 were added to Figs. 1 and 2, and reference number 38 was changed to 238 for consistency with the description. No new matter has been added.

In the Office Action, claims 25, 51, 75, 123, 130 and 136 were objected to as being dependent upon a rejected base claim, but were indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Examiner rejected claims 1-7, 9, 10, 17-22, 26-32, 34, 35, 42-48, 53-57, 59, 60, 67-72, 77-82, 89-94, 98-105, 107, 108, 115-120, 124-126, 131, 132, 137, 138, 145, and 158-167 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,458,638 ('638) to Kuslich in view of Kuslich '638. Claims 8, 13, 33, 38, 58, 63, 80, 85, 106, 111, 128, 134, 141, 142, 148, and 168 were rejected by the Examiner

under 35 U.S.C. § 103(a) as being unpatentable over Kuslich '638 in view of Kuslich '638 along with U.S. Patent No. 4,904,260 ('260) to Ray. Claims 11, 14-16, 23, 24, 36, 39-41, 49, 50, 61, 64-66, 73, 74, 83, 84, 86-88, 95, 96, 109, 112-114, 121, 122, 127, 129, 133, 135, 139, 140, 143, 144, 146, 147, 149-151, 153-157, and 169-172 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Kuslich '638 in view of Kuslich '638 and further in view of U.S. Patent No. 4,878,915 to Brantigan.

Claims 1, 26, 53, 77, 98, 124, 131, 137, 145, and 169 are the only independent claims pending in the present application. Independent claims 1 and 124, recite an implant with bone engaging means having an outer locus that is frusto-conical "along at least a portion of the length of said implant nearer said trailing end than said insertion end." Independent claims 26, 53, 98, and dependent claim 2, which depends from claim 1, are directed to an implant having a body that is frusto-conical "along a sufficient portion of said body that is adapted to contact the adjacent vertebral bodies when implanted in the spine so as to maintain an angulation of the adjacent vertebral bodies relative to one another." Independent claims 137 and 145 are directed to an implant having either a body or bone engaging means having arcuate portions with "a distance between said arcuate portions increasing from said first end to said second end along a sufficient portion of the length of said implant so as to maintain angulation of the vertebral bodies."

Applicant respectfully disagrees with the Examiner's interpretation of Kuslich '638. Fig. 15 does not teach a "frusto-conical spinal implant" as claimed by applicant. Instead, Kuslich states that:

"FIGS. 15-25 illustrate yet a further embodiment of an implant for use in spinal stabilization. As shown in those figures, the implant 120 ... includes a body portion 122 (shown in perspective in FIGS. 14 and 15) which is generally oval shaped in cross section.... The body 122 includes generally flat side walls 124, 126 joined by upper and lower semi-cylindrical arcuate ribs 128." (Kuslich '638, Col. 8, lines 39-47) (emphasis added).

In Kuslich '638, at FIG. 16 "body 122 is tapered at the leading end 133 with the side walls 124, 126 tapering inward at an angle  $A_7$  of preferably  $10^\circ$  each. Also, the upper and lower planar of the ribs 128 are tapered inwardly as best shown in FIG. 22 at a preferred taper angles,  $A_8$ , of about  $3^\circ$ . The edges defined by the juncture of walls 124, 126, ribs 128 and end 133 are rounded to facilitate insertion of implant 120." (Kuslich, Col. 8, lines 58-65). The "tapers  $A_7$  and  $A_8$  (FIGS. 16 and 22) and the rounded corners on leading end 133 assist in the insertion" of the implant. (Kuslich, Col. 9, lines 24-26).

The tapered leading end 133 of Kuslich '638 is not along a "sufficient portion of the implant length of said implant so as to maintain angulation of the adjacent vertebral bodies relative to one another" as recited in applicant's claimed invention. The adjacent vertebral bodies in Kuslich '638 are parallel. The Kuslich '638 implant does not have a substantially frusto-conical configuration along a sufficient portion of the implant that is adapted to contact the adjacent vertebral bodies when implanted so as to maintain an angulation of the adjacent vertebral bodies relative to one another as recited in applicant's claimed invention.

Independent claim 77 is directed to a spinal fusion implant having a body with a substantially cylindrical configuration and an outer surface including a plurality of posts having a head and a stem wherein the head is wider than the stem and the posts are spaced apart along at least a portion of the outer surface for engaging the implant to the adjacent vertebral bodies. Kuslich '638 discloses a cylindrical implant with threads on its external surface and an oval implant with arcuate ribs 128 on its exterior. (Kuslich '638, Col. 4, lines 13-20; and Col. 8, lines 39-52). Kuslich '638 does not disclose a spinal fusion implant with posts as claimed by applicant.

Independent claim 131 is directed to a spinal fusion implant being formed of a mesh-like material "capable of supporting two adjacent vertebral bodies in a spaced apart relationship to each other." No such structure is taught, disclosed or suggested by Kuslich '638 or Ray '260. Kuslich '638 discloses a threaded cylindrical implant with a hollow cylindrical shell 22 that surrounds and defines an interior chamber 24. Threads 26 and 28 are formed on the exterior of the shell and a plurality of openings 32 formed radially through the shell 22 and threads 26, 28. (Kuslich '638, Col. 4, lines 7-67). No mesh-like material is disclosed.

Ray '260 discloses a prosthetic intervertebral disc capsule having a diameter approximating the height of a human disc with an "outer layer 12 consisting of a network of strong, inert polymeric fibers interwoven with bioresorbable fibers which attract tissue ingrowth." (Ray '260, Col. 4, lines 3-7; Col, 8, lines 35-37.) Ray '260 does not disclose a spinal fusion implant. Ray '260 also does not teach, disclose, or suggest a spinal fusion implant being formed of a mesh-like material capable of supporting two adjacent vertebral bodies in a spaced apart relationship to each other as claimed by applicant.

Independent claim 169 recites a spinal fusion implant having a body "formed of a cancellous material capable of supporting two adjacent vertebral bodies in a spaced apart relationship to each other, said cancellous material having a plurality of interstices for holding fusion promoting material."

Brantigan '915 discloses a plug 11 having a knurled roughened peripheral surface 11b forming pyramid-like pits 11c for facilitating bone ingrowth; a device 31 with a pitted periphery 31b forming a myriad of small pores to facilitate bone ingrowth; a device 32 with longitudinally spaced circular ribs 32b that form dish-like prongs or barbs tilted toward the threaded end of the plug so that they will deflect to slide into the prepared sites; an implant 33 having an external periphery that is externally threaded 33b; and an implant 34 with a polymeric resin cover 34c having upright projecting bristles 34d. (Brantigan '915, Col. 6, lines 7-64). Brantigan '915 does not disclose a spinal fusion implant with posts as recited in applicant's claimed invention. Brantigan '915 also does not disclose a spinal fusion implant having a body with an outer locus larger than the space between two adjacent vertebral bodies to be fused and being formed of a cancellous material having a plurality of interstices and being capable of supporting two adjacent vertebral bodies in a spaced apart relationship to each other as recited in independent claim 169,

Applicant submits that Kuslich '638, Ray '260, or Brantigan '915, alone or in proper combination, do not anticipate, teach, or suggest, applicant's claimed invention in independent claims 1, 26, 53, 77, 98, 124, 131, 137, 145, and 169 or claims dependent therefrom. Accordingly, the rejection of claims 1-7, 9, 10, 17-22, 26-32, 34, 35, 42-48, 53-57, 59, 60, 67-72, 77-82, 89-94, 98-105, 107, 108, 115-120, 124-126,


131, 132, 137, 138, 145, and 158-167 under 35 U.S.C. § 103(a) over Kuslich '638 in view of Kuslich '638; the rejection of claims 8, 13, 33, 38, 58, 63, 80, 85, 106, 111, 128, 134, 141, 142, 148, and 168 under 35 U.S.C. § 103(a) as being unpatentable over Kuslich '638 in view of Kuslich '638 along with Ray '260; and the rejection of claims 11, 14-16, 23, 24, 36, 39-41, 49, 50, 61, 64-66, 73, 74, 83, 84, 86-88, 95, 96, 109, 112-114, 121, 122, 127, 129, 133, 135, 139, 140, 143, 144, 146, 147, 149-151, 153-157, and 169-172 under 35 U.S.C. § 103(a) as being unpatentable over Kuslich '638 in view of Kuslich '638 and further in view of Brantigan '915 have been overcome.

If there are any fees due in connection with the filing of this response, please charge our Deposit Account Number 50-1066. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the papers accompanying this response, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: December 5, 2000

By:   
Thomas H. Martin  
Registration No. 34,383  
Attorney for Applicant(s)

14500 Avion Parkway, Suite 300  
Chantilly, VA 20151-1101  
Telephone: 703-679-9300  
Facsimile: 703-679-9303